



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Antibodies with potent and broad neutralizing activity against antigenically diverse and highly transmissible SARS-CoV-2 variants.

Description of Technology:

Emergence of highly transmissible SARS-CoV-2 variants of concern that are resistant to current therapeutic antibodies highlights the need for continuing discovery of broadly reactive antibodies.

Scientists at the Vaccine Research Center of the National Institute of Allergy and

Infectious Diseases have engineered a group of human monoclonal antibodies that target epitopes on the receptor binding domain of SARS-CoV-2 spike protein. These engineered antibodies ultra-potently neutralize >12 variants of SARS-CoV-2, including the highly transmissible BA.4 and BA.5 subvariants of Omicron, as shown in a pseudovirus neutralization assay. These engineered antibodies target 3 distinct epitopes in the receptor binding domain of the spike protein and function by blocking ACE2 binding. These engineered antibodies are not impacted by spike mutations that knockout binding to other therapeutic antibodies, including E484K, N439K, Y453F, L452R and K417N. Several of the engineered antibodies are able to simultaneously bind to the spike protein and are compatible for use in combination therapies. In *in vitro* assays, these combinations were shown to decrease the appearance of escape mutants suggesting the potential to mitigate resistance development when used as combination therapy. Additionally, these engineered antibodies are better suited for manufacturing than the parental antibodies.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Treatment of SARS-CoV-2 infection

Competitive Advantages:

- Ultra-potent neutralization of currently identified SARS-CoV-2 variants including Omicron subvariants
- Combinations show the potential to mitigate resistance
- Improved manufacturability relative to parental antibodies
- Mechanism of Action – These antibodies bind to block ACE2 receptor binding to the SARS CoV-2 spike protein

Development Stage: Preclinical Research.

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Publications: None

Intellectual Property: HHS Reference Number E-185-2022 includes U.S. Provisional Patent Application Number 63/404,473 filed September 7, 2022.

Licensing Contact: To license this technology, please contact Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov.

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